

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY |) | MDL No. 1456 |
| AVERAGE WHOLESALE PRICE LITIGATION |) | Master File No. 01-12257-PBS |
| |) | Judge Patti B. Saris |
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| THIS DOCUMENT RELATES TO: |) | |
| State of California, <i>ex rel.</i> Ven-A-Care v. |) | |
| Abbott Laboratories, <i>et al.</i> |) | |
| 03-CV-11226-PBS |) | |
| |) | |

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT ABBOTT
LABORATORIES, INC.'S SEPARATE MOTION TO DISMISS THE FIRST AMENDED
COMPLAINT**

INTRODUCTION

Plaintiffs allege that California paid \$0.1177 per unit of Abbott's sodium chloride, while the market price for a Group Purchasing Organization (GPO) was \$0.0119 per unit (First Amended Complaint in Intervention ("FAC") ¶ 52). California's reimbursement, based on Abbott's published direct price, was almost ten times more than the GPO's price. *Id.*

Abbott first asserts that it did not engage in fraud because California did not sufficiently define the term "Direct Price" (DP). Abbott concedes, however, that California defines DP as the "price for a drug product *directly from a drug manufacturer* listed in the department's price reference source." (Former Cal. Wel & Inst. Code § 14105.46(a)(7), repealed 2004 (emphasis added).) When a price for a product obtained directly from a manufacturer is ten times higher for the government than it is for a private entity, a plausible case of fraud arises. Further examples of Abbott's pricing disparities are attached as Exhibit A to the FAC.

Contrary to Abbott's argument, the fact that it reported "direct prices," rather than average wholesale prices, does not provide grounds for dismissal under Federal Rule of Civil Procedure 9(b). Rather, Abbott's reporting of grossly inflated direct prices, which it knew California relied upon to set reimbursement levels, was a direct fraud perpetrated on the State.

Abbott further argues that California's false claims action violates the dormant commerce clause. The commerce clause, however, does not prevent California from prosecuting Abbott's fraud on its Medicaid program. In fact, the federal government requires that California police its Medicaid program and seek redress from any entity that defrauds the Medicaid program enacted to provide health care for children, the poor, elderly, and disabled. *See* 42 U.S.C. §§ 1396a(a)(30), (37), (61), §1396b(g), and this Court's discussion of the joint authority between state and federal governments in policing the drug rebate program, in *In re Pharm. Industr. Average Wholesale Price Litig.*, 321 F.Supp.2d 187, 195-97 (D. Mass. 2004). For each of these reasons, Abbott's separate motion should be denied.

I. THE COMPLAINT CLEARLY DESCRIBES ABBOTT'S FALSE PRICE SCHEME

California's FAC alleges that, in order to market their products, Defendants, including Abbott, intentionally created a substantial "spread" between the prices they reported for their products and the actual prices that providers were charged. FAC ¶¶ 43-48, 53. Exhibit A attached to the FAC of the complaint specifies the "direct prices," reported by Abbott and those prices it actually charged private entities.

Abbott's argument is based on an incomplete description of the applicable California statutory and regulatory scheme. California Welfare & Institutions Code section 14195 states in part: "[T]he Legislature hereby establishes an open drug formulary under the Medi-Cal program wherein

a beneficiary may receive the most appropriate, most effective, *and most cost-efficient* drug available for the treatment of his or her illness.” (Emphasis added). The applicable regulation during the period prior to 2002, when direct prices were used by DHS for reimbursement, Cal. Code Regs. tit. 22, §51513(a)(6), states in part: “Estimated Acquisition Cost (EAC) for a medical supply product means the Average Wholesale Price *or such other price as the Department determines to be the price generally and currently paid by providers* for a standard package.” (Emphasis added). In turn, Cal. Code Regs. tit. 22, §51513.5(a) then provides that “EAC shall be the direct price listed for a standard package in the Department’s primary price reference source . . .” with respect to certain enumerated companies, including Abbott. In short, as Abbott has long known, the statute and regulations expressly provide that its reported “Direct Prices” should be its actual prices to providers, or the “price generally and currently paid by providers” and not some mythical “list price” that bears little, if any, relation to market prices.

II. CALIFORNIA’S REGULATION OF DRUG REIMBURSEMENT PRICES DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

First, California’s regulation of its drug reimbursement prices falls within the long-established “market participant” exception to commerce clause analysis. Second, the State’s acts do not directly regulate Interstate Commerce and therefore are presumptively valid under the Commerce Clause. Third, the State has not imposed burdens on interstate commerce that are clearly excessive in relation to the local benefits. At a minimum, there are factual issues in that regard that cannot be presently decided.

Abbott ignores the critical fact that the claims here arise from the State’s participation in the market for drug products, and therefore fall within the market participant exception to commerce

clause analysis. “That doctrine differentiates between a State’s acting in its distinctive governmental capacity, and a State’s acting in the more general capacity of a market participant; only the former is subject to the limitations of the negative Commerce Clause.” *New Energy Co. v. Limbach*, 486 U.S. 269, 277 (1988). *See White v. Massachusetts Council*, 460 U.S. 204, 208 (1983); *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 810 (1980). Those cases stand for the proposition that a State does not violate the dormant commerce clause when it acts in its “proprietary capacity as a purchaser or seller” even if it discriminates against or burdens interstate commerce. *Camps Newfound/Owatonna, Inc. v. Town of Harrison, Maine*, 520 U.S. 564, 592 (1997).

The State’s acts here do not directly regulate interstate commerce and, therefore, are presumptively valid under the dormant Commerce Clause. Unlike the circumstances in *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573 (1986), upon which Abbott relies, California’s enforcement of its laws only concerns the overcharges that it has suffered and does not regulate the prices that Abbott charges other States or out-of-state commerce more generally.

Abbott contends California is seeking “to require that the discounted [i.e., actual transaction] price be published and that products be sold at that price throughout the fifty states.” (Abbott Mem. at 3.) Nothing in the California statutes or regulations purports to set prices outside the State or impose California’s definitions¹ of commercial terms, however. Other than vague assertions that California is trying to control prices throughout the country, Abbott fails to provide specific examples of infringement on interstate commerce. In addition, Abbott concedes

¹The regulations expressly provide that “[w]ords shall have their usual meaning unless the context or a definition clearly indicates a different meaning.” (Cal. Code Regs., tit. 22 §51513.5.)

that Medi-Cal “may have been the only state Medicaid program to use Direct Price.” Abbott’s position is, in essence, that anytime a State uses commercial terms in its statutes it is inherently and directly regulating commerce outside its borders. Given that nothing in the California statute or regulations purports to affect prices other than those paid by the State itself with respect to in-State transactions, there is no support for the argument that California has regulated interstate commerce.

Under *Brown-Forman* and *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), the State’s regulations must be upheld unless the burden imposed on interstate commerce “clearly exceeds the local benefits.” *Brown-Forman*, 476 U.S. at 560, citing *Pike*, 397 U.S. at 142. Abbott does not begin to satisfy that standard. Abbott concedes, as it must, that “California has a legitimate interest in setting Medi-Cal reimbursement rates.” Mem at p. 5. But Abbott complains that California should have used its “own independent regulatory benchmark” rather than a preexisting commercial term. Clearly, the Commerce Clause does not proscribe States from using pre-existing commercial terms. In any event, the notion that “Direct Price” was an industry term of art, which California has somehow twisted into a new meaning, is wholly unsupported. California’s use of the term has not interfered with Abbott’s efforts to communicate its true prices to its customers. Abbott asserts that California’s allegations of false drug pricing represents a burden on interstate commerce, when, in fact, the suit seeks only to remedy fraud. Any incidental restriction on Abbott’s ability to carry out fraudulent drug pricing beyond California’s borders is not prohibited under the dormant commerce clause of the Constitution.

CONCLUSION

For the reasons stated above, Abbott’s Motion to Dismiss the FAC should be denied.

Respectfully submitted,

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Dated: March 2, 2006

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CERTIFICATE OF SERVICE

I, Nicholas N. Paul, hereby certify that on March 2, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT ABBOTT LABORATORIES, INC.'S SEPARATE MOTION TO DISMISS THE FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: March 2, 2006

/s/ Nicholas N. Paul
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